Subject: Please Sign & Mail Today
Date: Mon, 5 Apr 1999 09:36:48 -0500
From: "Toxic Discovery Network, Inc." <ToxicDiscovery@email.msn.com>
To: <ToxicDiscovery@email.msn.com>

Dockets Management Branch

Food and Drug Administration

Department of Health and Human Services, rm 1-23

12421 Parklawn Dr.

Rockville. MD 20857

The undersigned submits this petition to request the Commissioner of Food and Drugs to revoke the implantation of silicone gel-filled breast implants in women. Excessive failure rates pose an unreasonable risk to the health of women. A failure rate of 5 percent was regarded as "not a safety standard that the FDA can accept" according to former FDA Commissioner David Kessler (JAMA 270: 2607, 1993). A failure master curve from eleven research papers of 1,652 explanted prothesis, shows a significant direct correlation of failure rate with implant time and can be used to predict a *failure rate of 50 percent at 8 years.*

High failure rates of silicone gel-filled breast implants which leak and spread silicone, silica, or its components to all parts of the body with toxic results, demands an immediate ban by the FDA until adequate, valid, and reliable safety data is established. FDA's compilation of the literature assessing risks associated with this non-lifesaving device illustrate the necessity of a ban for this device until a safer and more effective device is introduced.

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99P-2147

C2

Subject: Ban - 2
Date: Mon, 5 Apr 1999 09:40:26 -0500
From: "Toxic Discovery Network, Inc." <ToxicDiscovery@email.msn.com>
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Food and Drug Administration

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The undersigned submits this additional information to support the petition to ban silicone breast implants:

In 1997, Dr. Louise Brinton in a published review of Breast Implants and Cancer (Journal of NCI 9/17/97) reported "Silicone gel has been found to migrate into both surrounding and distant tissues as a result of rupture or bleed, with reports of evidence of silicone found in the breast, implant capsule, axillary lymph nodes, arms, fingers, groin, blood and liver ... recent evidence, has documented that it is immunogenic."

Recent Houston Baylor College of Medicine published research report:

1. Breast Implant material (not pure polymer, but an siloxane oligomer, which is an incomplete unit) contains platinum. Lykissa, E.D., et al, Release of low molecular weight silicones and platinum from silicone breast implants, Analytical Chemistry, Vol. 69, No. 23, Dec. 1, 1997.

2. These materials migrate outside the implants.

3. The siloxane oligomers, when injected under the skin of mice are "taken up and deposited in the organs and their fat. We have found these compounds in the lymph nodes, uterus, ovary, fat and seven other organs."

The compounds persist for "approximately 40% of the life span of a mouse." Kala, S.V., et al. Low molecular weight silicones are widely distributed after a single subcutaneous injection in mice, American Journal of Pathology, Vol. 152, No. 3, March 1998

4. "Siloxane oligomers are toxic to mice...If one injects these compounds into the abdomen of female mice they produce severe liver and lung injury and mice die approximately 7 days after the injection." Lieberman, M.W., et at, Cyclosiloxanes produce fatal liver and lung damage in mice, environmental Health Perspectives, Vol. 101, No. 2, February 1999 Dr. Michael Lieberman, chairman of the Department of Pathology, stated in a press conference on 12/1/98 "Injection of approximately 0.2 ml of D4 (about 4% of a teaspoon) will kill approximately 50% of the mice In 7 days. This degree of toxicity Is about the same as that of carbon tetrachloride and trichloroethylene, two compounds that are widely recognized as model toxins and in fact are used by many researchers in their work to understand how toxic chemicals harm the body. Let me conclude by noting that I believe there is significant evidence that components of breast implants are highly toxic and may cause serious health effects."

The safety and efficacy of this device has never been proven by the manufacturers, as is required by law. The integrity of the data supplied for PMA approval by Mentor Corporation should be questioned due to violations of Good Manufacturing Practices found in FDA inspections, and the necessity of the FDA to issue a Consent Decree with this company. Reliability and validity of clinical trial data submitted for PMA approval should also be in question due to low follow up rates and reports of women enrolled in the study who's complications and experiences are not

accurately reflected in the study data. Additionally, recent published research indicates an increase in failure rates over time, thus a five year study will not demonstrate true safety and effectiveness of the device.

We do not know the severity of the complications from leakage and rupture which may include "atypical" autoimmune and neurological disease, chemical toxicity, cancer, and organ involvement. Breast Cancer patients may be even more vulnerable and at risk due to their weakened immune systems.

Though epidemiological studies done to date have not been able to show a conclusive link to silicone breast implants and classical autoimmune disease, there is general agreement that a definitive study has yet to be published. Researchers and Physicians who treat large numbers of breast implant recipients recognize silicone breast implants to be the common denominator in the cluster of symptoms and diagnoses seen in these women.

If silicone gel-filled implants are banned, women will still be able to choose saline-filled/silicone shell implants for reconstruction. However, it should be noted that these are class 3 devices for which safety and efficacy has yet to be proven. Adequate informed consent should be obtained and the FDA should consider if the risk benefit ratio is acceptable for cosmetic patients, until the safety of the device has been established.

ENVIRONMENTAL IMPACT

We request an environmental assessment under Sec. 25.31. I believe that there will be a positive environmental impact when silicone gel implants are removed from the market because there will be less toxic waste to dispose of when implants are removed, and during the manufacturing process. I believe women and their children will experience less toxic poisoning

and environmental injury when gel implants are no longer placed in their bodies or when silicone, silica, or its components are passed in the placenta or in breast milk.

ECONOMIC IMPACT

Revoking the implantation of silicone gel implants will help balance the budget and reduce the deficit. Less money will have to be paid out when former hard-working productive women implanted with silicone gel become disabled, lose their jobs and insurance, and can no longer care for themselves and their families. Banning silicone breast implants should have a favorable economic impact on the individual considering gel implants in long term health care savings. Some insurance companies are denying women health insurance coverage if they have or have had breast implants (Blue Cross/Blue Shield of Texas, Underwriter Guidelines- Health Insurance 1996). The economic burden of providing health care to these women will fall upon our government. Statistics for severe diseases found in breast implant recipients in the MDL Revised Settlement Document a higher incidence of serious autoimmune diseases in breast implanted women. The economic impact of these diseases in this country is in the billions of dollars.

A possible negative impact to the economy might be a loss of income for the Plastic Surgeons who have come to depend on the easy money generated by breast implants, the repeat surgeries that they require, and the high cost of explantation when rupture or severe gel bleed occurs. Women are not given true risk ratios or accurate information in order to make an informed choice or to give an informed consent. It is a conflict of interest for a Plastic Surgeon to advise a patient on elective surgery,

for which he stands to enjoy financial gain, when that choice may damage a woman's health and the health of her unborn children. Women can only give true informed consent when they have all the facts. All the facts are not in.

The physical insult to a woman's body from breast cancer should not be followed up with the physical insult of implanting a dangerous toxic foreign body with such a high failure rate of both rupture and contracture. This is contrary to public health. A healthy female should not be implanted with a non-lifesaving, class 3, unapproved device. This is contrary to public health.

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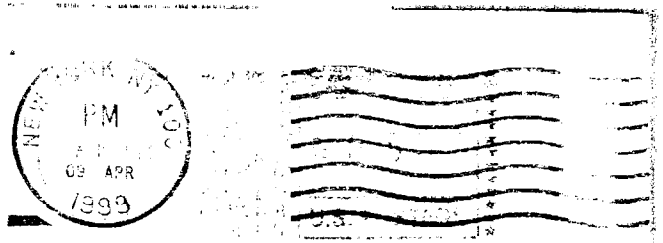

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